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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,786	12/18/2000	Eiji Hayakawa	2500.5	4015

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/647,786

Applicant(s)

HAYAKAWA ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Receipt is acknowledged of the Extension of Time and the Response, both received by the Office on September 30, 2002.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,047,866 to Shah. Shah discloses an automatic self-lubricating rotary tablet press. Shah teaches that the use of lubricants in tablet formulations is known, but there are disadvantages associated with it. Instead, Shah teaches a tablet press, using punches and dies, wherein a lubricator is attached as part of the compression equipment, and applies controlled amounts of lubricant to the die and punch faces (c 4, claims 1). Furthermore, Shah teaches that the lubricant is applied by spraying onto the punch faces and dies (c 4, claims 4). It is the position of the examiner that this disclosure anticipates the limitations of applicant's claims.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,461,195 to Sebastiani. The above discussed patent (Shah) states that Sebastiani teaches a method for spraying lubrication of the punches of a single station tableting press (Shah, c 1, l 38-

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40). Additionally, Sebastiani teaches a lubricating apparatus for applying lubricating powder to the punches of a tableting machine in order to lubricate the free faces of the plugs to produce tablets having a smooth and solid surface (c 1, lines 15-50). Lastly, Sebastiani teaches that the lubricant is sprayed through a conventional air compressor (c 2, l 28-30). It is the position of the examiner that these teachings anticipates applicant's claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah or Sebastiani, as discussed above, and in view of the following comments. Shah and Sebastiani teach a method for spraying a lubricant onto the punches and dies of a compression tableting machine, in order to achieve better tableting. Neither reference specifically states that the punches and dies are located inside a spray chamber, but they both teach that the lubricant is applied through a spraying process. Therefore, one would expect that there is a spray chamber present in the apparatus. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use the method and apparatus taught by Shah or Sebastiani in order to lubricate the punches and dies of a compression tableting system. The expected result would be a compressed tablet which does not adhere to the punches or dies during processing.

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Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed September 30, 2002 have been fully considered but they are not persuasive. Applicant argues that their invention is not simply a tableting method characterized by merely substituting so called "external" lubrication methods for prior internal lubrication. Instead, Applicant argues, their invention provides a method which has succeeded in manufacturing tablets by compressing materials that have been impossible to be molded in the prior art, such as materials which would be denaturalized or inactivated when tabletted at high pressure, or solid dispersions of powdered or granulated materials. Applicant further argues that their invention unexpectedly provides that the tablets of powdered or granulated medicinal substances are more readily dissolved in water such that both disintegration time and absorption is improved.

The examiner appreciates applicant's summary of their instant application. However, this is not persuasive in overcoming the rejection. In order to overcome the instant rejections, it is necessary that Applicant provide comparative scientific data demonstrating that the method discussed by the prior art differs from the method claimed by Applicant. It is the position of the examiner that the method, as claimed now, is taught by the prior art. As stated by Applicant, in his response, "the present invention is characterized by forming lubricated surfaces on the punches and dies used for tableting, wherein even powdered or granular material comprising [a] compound which is denaturalized or inactivated when tabletted at [a] high pressure can be

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compressed even when a tableting pressure is restricted below the pressure required to practice the prior art. Therefore, the present invention enables those of ordinary skill in the art to utilize material[s] which [have] been impossible to be compressed and molded thereby improving preparation technique[s] to attribute development of disparate pharmaceutical products.” The examiner appreciates that Applicant has found that this process is successful in tableting products which are not normally tabletable. However, this does not render patentable distinction to the claim language. In order to anticipate the instant claims, the examiner need only find a reference that teaches the method, as claimed. It is not necessary for the method to teach all of the positive findings and results that this method made possible. In order to overcome the prior art rejections, the following are recommended. (1) Add additional method steps to the instant claims that differentiate it from the prior art. The current claims are too broad. (2) Add the specific drugs that this new method is successful with, and provide comparative scientific evidence that the prior art method would not be successful with those drugs.

For the above reasons, the rejections are maintained.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam  
Patent Examiner  
Art Unit 1615  
December 6, 2002

THURMAN K. PAGE  
SUPERVISOR  
TECHNOLOGY CENTER 1600  
PATENT EXAMINER